Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Narketan-10 100 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Ketamine (as ketamine hydrochloride)	100.0	mg

Excipients

Benzethonium chloride (as a preservative)	0.1	mg
Disodium edetate (as an antioxidant)	0.1	mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless sterile aqueous solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cat, dog, horse and donkey.

4.2 Indications for use, specifying the target species

The product may be used as a sole agent for restraint and minor surgical procedures where muscle relaxation is not required in the cat. The product may be used in conjunction with medetomidine in the dog and cat, in conjunction with xylazine in the dog, cat, horse and donkey and in conjunction with detomidine in the horse to induce anaesthesia.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active ingredients.
The product is metabolised by the liver and excreted via the kidney and hence should not be used in animals with hepatic or renal dysfunction or failure.
Do not use the product as a sole agent in horses, donkeys and dogs.

4.4 Special warnings for each target species

It is important that both induction and recovery should occur in quiet and calm surroundings.
It is generally accepted as good anaesthetic practice to starve animals for a period of 12 hours prior to anaesthesia where possible.
A small proportion of animals have been reported to be unresponsive to ketamine as an anaesthetic agent at normal dosages.
Use of premedicants should be followed by a suitable reduction in ketamine dosage. This reduction may be up to 50%.
Care should be taken when using ketamine-halothane combinations since the half-life of ketamine is prolonged.
Use of the intramuscular route may be associated with pain.

4.5 Special precautions for use

(i) Special precautions for use in animals

Cat:
Ketamine may cause salivation in cats. Atropine premedication may reduce this side effect.
Muscular twitching and mild tonic convulsions have been recorded in the cat at recommended dose rates. These subside spontaneously but may be prevented by use of acepromazine or xylazine premedication, or controlled by use of acepromazine or ultra short acting barbiturates in low doses.
When used with xylazine for anaesthesia in cats, the patient should be supervised for 15-30 minutes post operatively to ensure a regular respiratory pattern. Should apnoea occur, gentle pressure with finger and thumb to the nasal septum will stimulate immediate inspiration.

Horse and donkey:
Do not use the product as a sole agent in the horse and donkey.

Horses must be quietly and carefully handled during the administration of anaesthetic agents.

With the product anaesthesia, the eyes remain open and the pupils dilated. The eyes may be protected by application of a bland ophthalmic ointment or covering with a damp gauze swab.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

This is a potent drug – particular care should be taken to avoid self-administration. In the event of accidental self-administration, seek urgent medical attention and show the label and other product literature. Do not drive.
Advice to doctor: do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.
Wash off splashes from skin and eyes immediately.

4.6 Adverse reactions (frequency and seriousness)

Cats may show excessive salivation, hypotension, muscle twitching or mild convulsions.

4.7 Use during pregnancy, lactation or lay

Use is not recommended during pregnancy
Combinations with xylazine and detomidine should not be used in the last trimester of pregnancy. Combinations with medetomidine should not be used in pregnant cats.

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

For intravenous, intramuscular and subcutaneous injection only.

It should be noted that dosage and routes of administration vary widely between species.

Due to the low doses required for small animals, an insulin type syringe should be used for dose measurement.

Dog-Xylazine/Ketamine:
Dosage and administration: Administer xylazine at a dose rate of 1 mg/kg by intramuscular injection. Immediately administer the product at a dose rate of 15 mg/kg by intramuscular injection.

Induction time to loss of the pedal reflex takes about 7 minutes with duration of anaesthesia lasting about 24 minutes. Arousal time, from time of injection to pedal reflex return, takes about 30 minutes.

Dog-Medetomidine/Ketamine:
Dosage and administration: Administer medetomidine at a dose rate of 40 µg/kg and the product at 5.0 or 7.5 mg/kg (depending on the duration of anaesthesia required) by intramuscular injection.

Ketamine* **Dose mg/kg**	**Induction time (to loss of pedal reflex) minutes**	**Duration of anaesthesia minutes**	**Arousal time (from time injection to pedal reflex return) minutes**
5.0	11	30	40
7.5	7	51	58

* when combined with medetomidine at 40 µg/kg.

Cat-Ketamine:
Dosage and administration: The product may be used by intravenous or subcutaneous injection, but intramuscular injection is the recommended route. The dose is 11-33 mg/kg depending on the degree of restraint or surgical interference that is intended.

The following dosages are indicated as a guide but may need to be adjusted depending on the physical condition of the patient and the conjoint usage of sedatives and premedicants.

Dose mg/kg	Clinical procedures
11	Minor restraint
22-33	Minor surgery and restraint of fractious cats
In conjunction with supplemental sedatives or anaesthetics	
22-33	Laparotomy, orthopaedics etc.

Vomiting is unlikely to occur when the product is used alone, however food should be withheld from cats for several hours prior to anaesthesia where possible. Induction and recovery should be allowed to occur in quiet and calm surroundings. Duration of the product anaesthesia is 20-40 minutes and recovery takes place over a 1-4 hour period. Both are prolonged by the use of premedicants.

Ketamine-supplement combinations in the cat: Atropine premedication is generally recommended at 0.05 mg/kg to reduce salivation. Endotracheal intubation can be achieved during use of the product for anaesthesia. Inhalation anaesthesia may be maintained by suitable combinations of methoxy flurane, halothane, nitrous oxide and oxygen.

Acepromazine (0.11 mg/kg) and atropine (0.05 mg/kg) by intramuscular injection may be used as a premedicant prior to administration of the product at 22 mg/kg, or may be administered simultaneously with the product.

Cat-Xylazine/Ketamine:
Dosage and administration: Xylazine (1.1 mg/kg) and atropine (0.3 mg/kg) by intramuscular injection may be used 20 minutes prior to administration of the product at 22 mg/kg. Xylazine may induce vomiting up to 20 minutes after administration. Onset of anaesthesia after intramuscular injection of the product takes 3-6 minutes.

A xylazine/ketamine combination produces a deeper anaesthesia with more pronounced respiratory and cardiac effects and a longer recovery period than acepromazine/ketamine combinations.

Cat-Medetomidine/Ketamine:
Dosage and administration: Medetomidine should be administered at a dose rate of 80 µg/kg by intramuscular injection. This should be followed immediately by the intramuscular injection of the product at a dose rate of 2.5 mg up to a maximum of 7.5 mg ketamine/kg (depending on the duration of anaesthesia required).

Onset of anaesthesia is 3-4 minutes. The duration of surgical anaesthesia varies between 30-60 minutes and is related to the dose of the product used. If required, anaesthesia may be prolonged with halothane and oxygen with or without nitrous oxide.

Atropine is not normally necessary when using a medetomidine/ketamine combination.

Horse and Donkey-Xylazine/Ketamine:
For the production of short term anaesthesia suitable for minor surgical interference or for induction prior to inhalation anaesthesia. The product alone should never be used as a sole anaesthetic agent.

Dosage and administration: Xylazine should be administered by slow intravenous injection at a dose rate of 1.1 mg/kg. The horse should appear sedated by 2 minutes post injection. The product should be administered at this stage. It is recommended not to delay the injection longer than 5 minutes after xylazine administration. The product should be administered as an intravenous bolus at a dose rate of 2.2 mg/kg.

Induction and recumbency takes 1-2 minutes. Muscle jerking may occur in the first minutes, but this usually subsides.

Anaesthesia is variable in duration, lasting 10-30 minutes, usually less than 20 minutes. Horses usually stand 25-45 minutes after induction. Recovery is usually quiet, but may occur suddenly. It is important therefore that short duration interferences only are attempted, or arrangements to prolong anaesthesia are made. For longer periods of anaesthesia, intubation and maintenance by inhalation anaesthesia can be used.

It is important that both induction and recovery should occur in quiet and calm surroundings.

Horse-Detomidine/Ketamine:
For the production of short term anaesthesia suitable for minor surgical interference or for induction prior to inhalation anaesthesia. The product should never be used as sole anaesthetic agent.

Dosage and administration: Detomidine should be administered by intravenous injection at a dose rate of 20 µg/kg. The horse should appear sedated by five minutes post injection. At this stage the product should be administered at a dose rate of 2.2 mg/kg as an intravenous bolus.

Onset of anaesthesia is gradual; most horses take approximately one minute to become recumbent. Large, fit horses may take up to three minutes for recumbency. Anaesthesia continues to deepen for a further 1-2 minutes and during this time the horse should be left quietly.

Horses regain sternal recumbency approximately 20 minutes post ketamine injection giving a surgical anaesthesia duration of 10-15 minutes.

Should it be necessary to prolong anaesthesia, thiopentone sodium may be administered intravenously in boluses of 1 mg/kg as required. Total doses of 5 mg/kg (five 1 mg/kg increments) have been given. Total doses greater than this may reduce the quality of recovery. Thiopentone can also be administered in increments if sufficient depth of anaesthesia is not achieved.

The horse may be ataxic if encouraged to stand prematurely and so should be left to stand in its own time.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

If necessary, suitable artificial aids to maintain ventilation and cardiac output should be used until sufficient detoxification has taken place to enable a return to adequate spontaneous ventilation and cardiac activity. Pharmacological cardiac stimulants are not recommended, unless no other supportive measures are available.

4.11 Withdrawal period(s)

UK only: Not to be used in horses and donkeys intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

Ireland only: Meat and offal: 24 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetics
ATC vet Code: QN01AX03

5.1 Pharmacodynamic properties

The product is a potent dissociative anaesthetic agent for use by intramuscular, subcutaneous or intravenous injection.
The product induces a state of catalepsy with amnesia and analgesia; muscle tone is maintained including the pharyngeal and laryngeal reflexes. The heart rate, blood pressure and cardiac output are increased; respiratory depression is not a noticeable feature. All these characteristics may be modified if the product is used in combination with other agents.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzethonium Chloride
Disodium Edetate
Sodium Hydroxide
Water for Injections

6.2 Major incompatibilities

Do not use ketamine with barbiturates, diazepam, xylazine or detomidine in the same syringe or infusion bag.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Type I, colourless, neutral, glass vials closed with a bromobutyl rubber stopper and a flip-off cap composed of aluminium/polypropylene.
Pack sizes are 10 ml and 50 ml volumes respectively.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/055/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 2000
Date of last renewal: 30 September 2010

10 DATE OF REVISION OF THE TEXT

August 2019